

Oncopeptides Operational Update Q1 2020

“Setting Stage for Commercialization”

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Recent highlights

COVID-19: Pivotal studies not affected but signal seeking trials paused

- Temporary recruitment pause for bortezomib arm in ANCHOR and in BRIDGE as well as AL Amyloidosis study and initiation of new studies such as LIGHTHOUSE postponed

O12-M-1 data published in Lancet Haematology

- Favourable editorial in same issue

Strong final top-line data from HORIZON presented

- ORR of 30% in ITT population and 26% in triple-class refractory RRMM patients

NDA submission for triple-class refractory MM on track

- Application for accelerated approval in triple-class refractory MM on track for Q2-2020

Phase 3 study OCEAN fully recruited

- Successful completion of enrollment in the pivotal phase 3 study OCEAN with 450 patients
- Top line results will be presented H2 2020

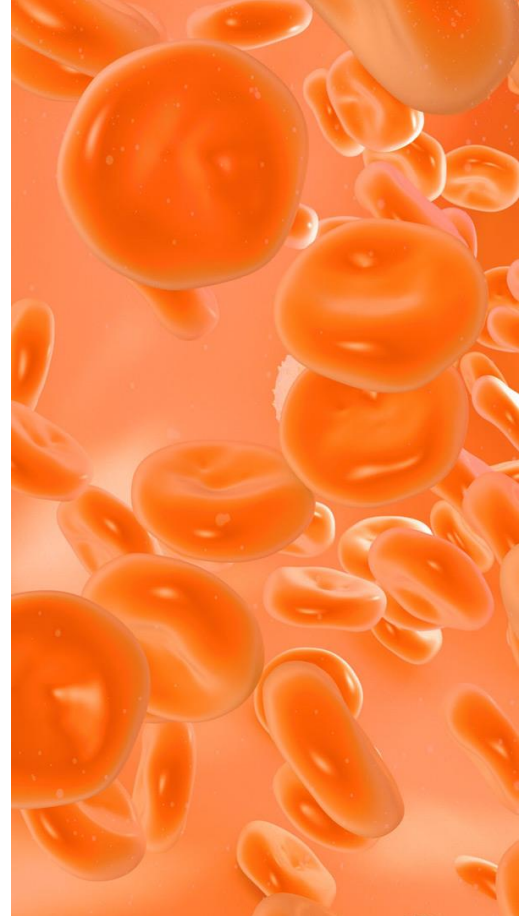
Pivotal HORIZON data validate our PDC technology platform

- Open up for new cancer indications with two new drug candidate entering clinical development 2020 and 2021

Preclinical and clinical data to be presented at multiple upcoming conferences

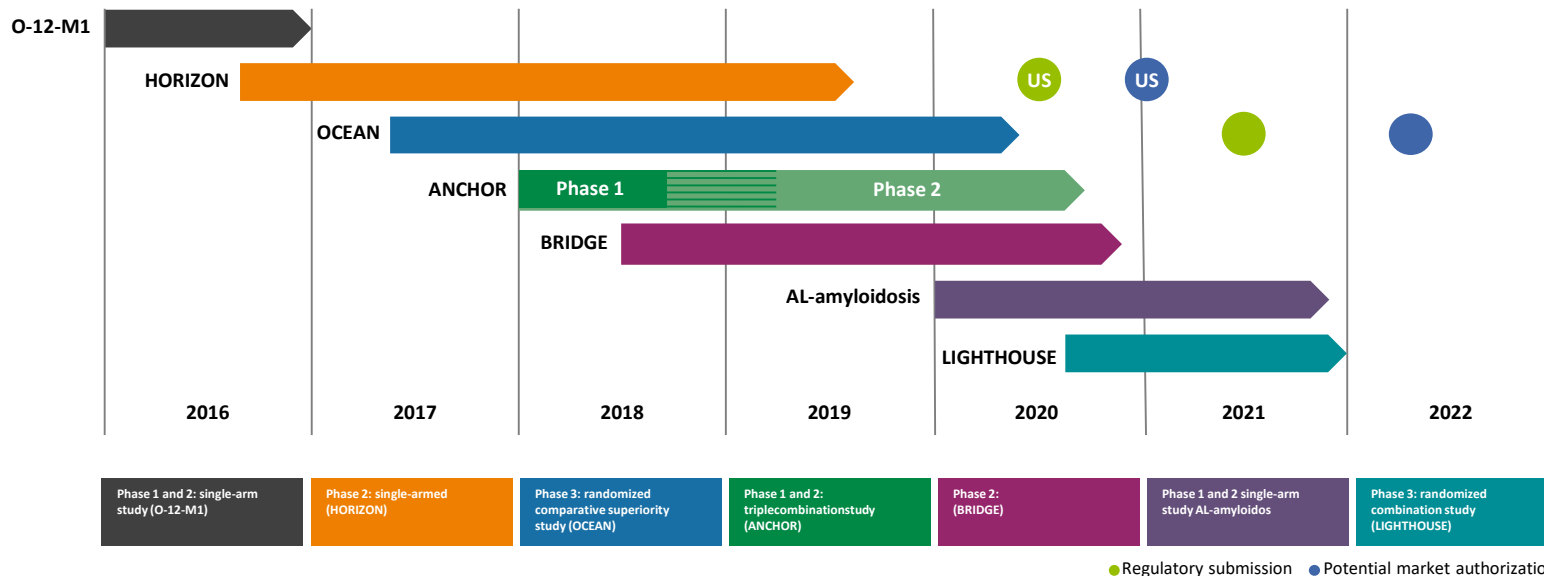
Balance sheet strengthened

- Directed share issue raised proceeds of SEK 1.4 billion before issue costs in May

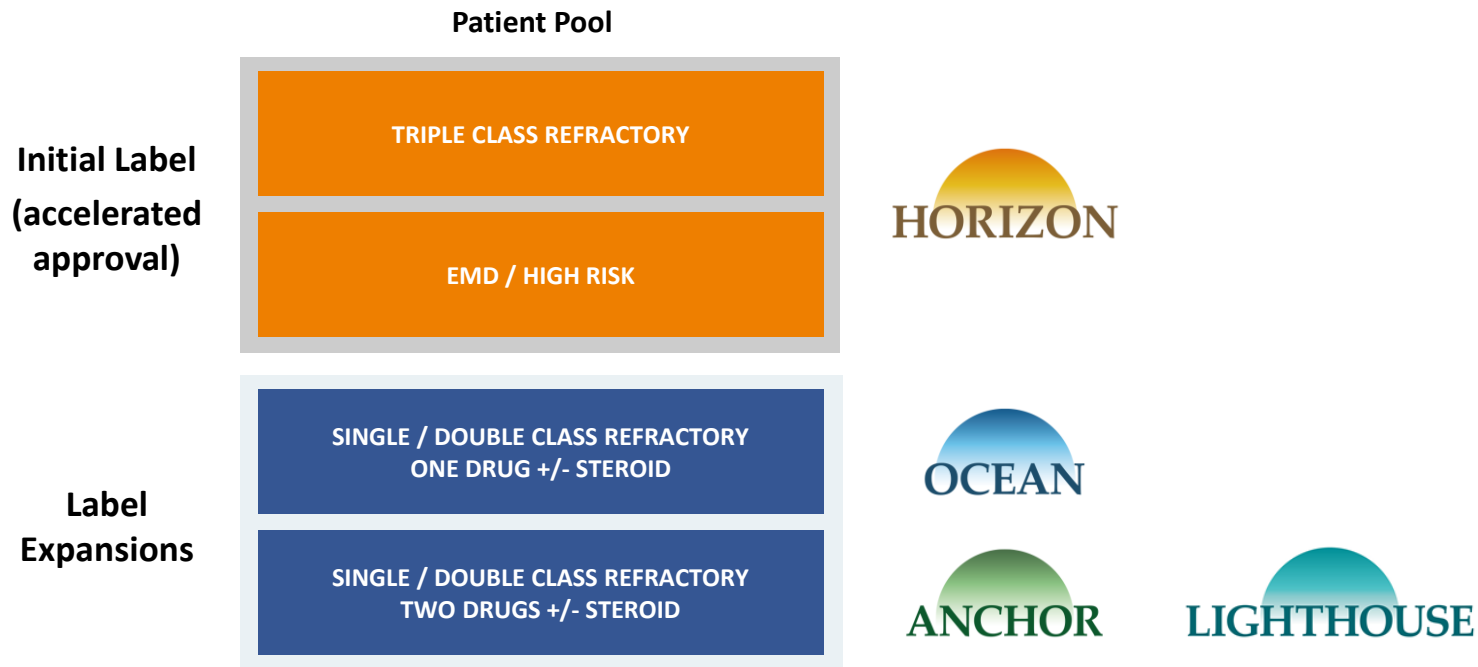


Melflufen in clinical development

Provided a positive regulatory assessment, the clinical program will provide a broad set of data including its effect in different patient groups.

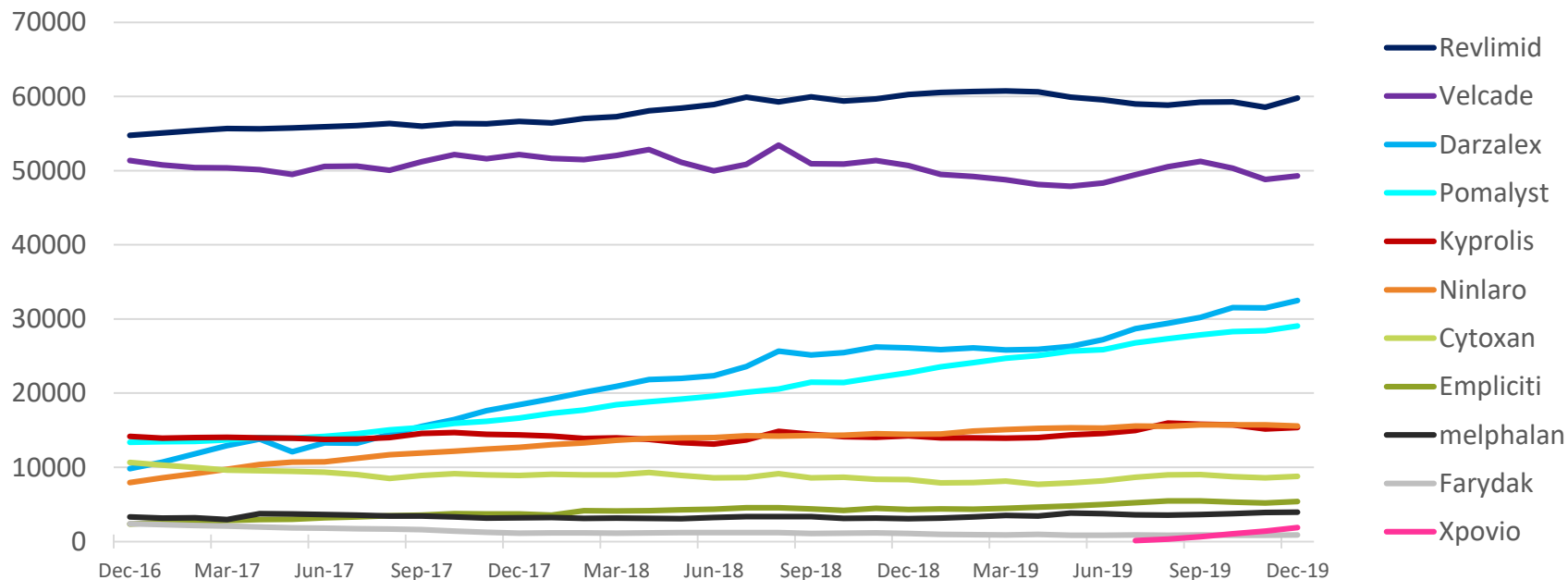


Label journey with current development program in myeloma

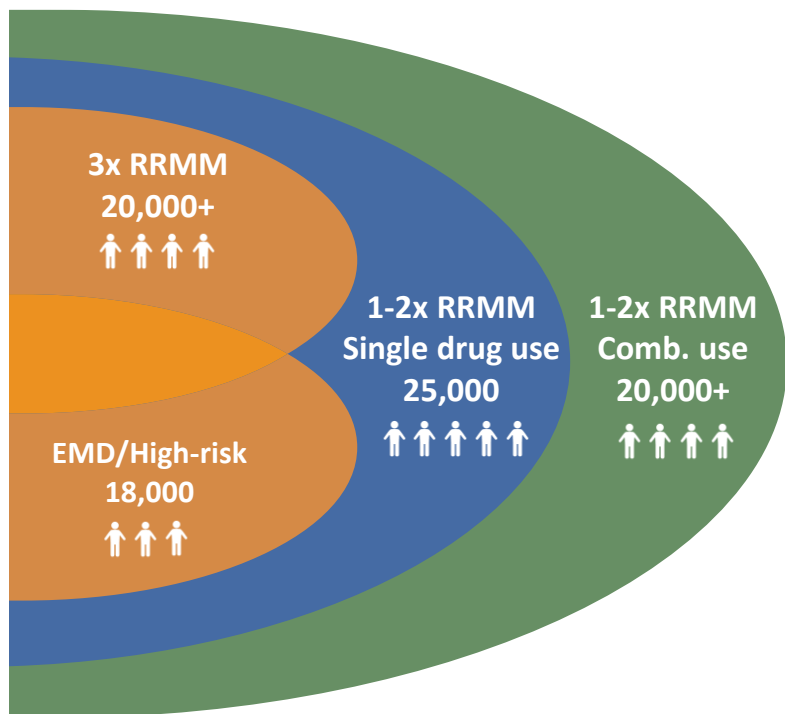


Newer products used in addition to older products as survival improves

US MM # of Patients by Product



The market opportunity is significant for melflufen's planned label journey in RRMM (US patient numbers)



Clinical Program



Anticipated label in triple-class refractory patients.



Head-to-head superiority study with the most commonly used regimen in RRMM. Majority of RRMM patients use single agent +/- steroid.

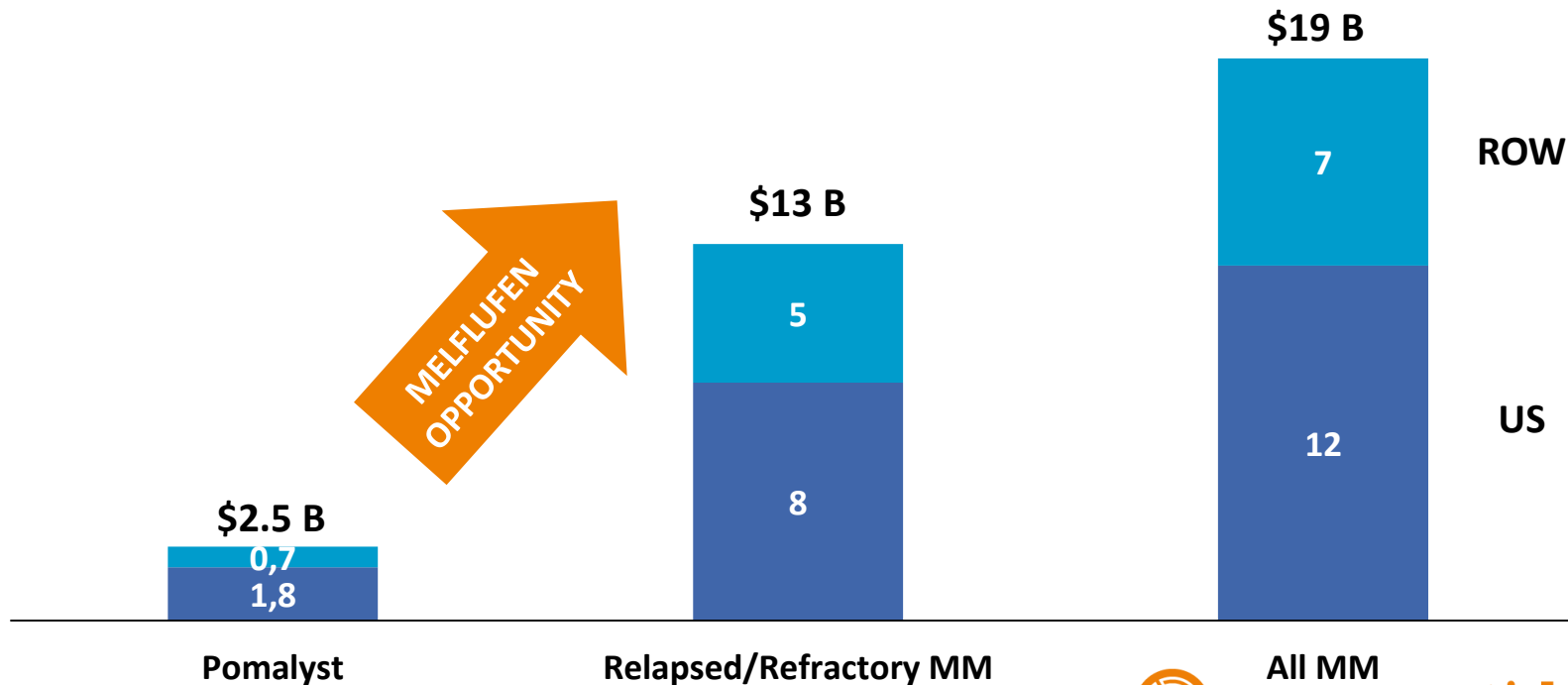


Combination with PI or anti-CD38 opens up 2L+ combination treatment opportunity.

Source: Patient numbers based on IntrinsiQ analysis.

Melflufen opportunity in Relapsed Refractory Multiple Myeloma

– 2019 Multiple Myeloma Net Sales Breakdown



Source: EvaluatePharma, Intrinsiq, company analysis



Editorial in Lancet Haematology regarding melflufen

Is there a role for new drugs with alkylating properties in multiple myeloma?



Multiple myeloma, a complex disease originating in plasma cells, was primarily treated with melphalan until the last years of the 20th century. Advances in knowledge of the biology of the disease have led to the introduction of new drugs, and its transition of new drugs from the relapse setting to first-line treatment has been fast and as a result, most patients with multiple myeloma will receive proteasome inhibitors

intravenously every 4 weeks in combination with weekly dexamethasone can lead to clinical improvement (overall response rate was 31% [14 of 45 patients; 95% CI 18–47]; median progression-free survival was 5.7 months [95% CI 3.7–9.2]; and overall survival was 20.7 months [11.8 to not reached]). The most common toxicities were haematological toxicity and grade 3–4 thrombocytopenia and neutropenia.

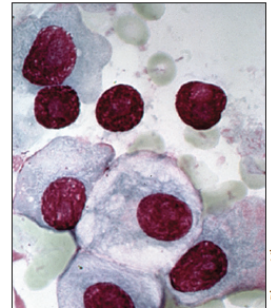


Photo Library

Final HORIZON data in triple-class refractory RRMM



Independent Review Committee (IRC) data

Primary End-Point	Investigator Ass. Data Jan 14 th	IRC Data Jan14 th	Incl. unconfirmed Responses Jan 14 th
Overall Response Rate (ORR) – ITT n=157	29%	30%	31% (inv. and IRC)
ORR – 3x RRMM n=119	26%	26%	27% (inv. and IRC)
ORR – EMD n=55	24%	27%	NA

Note: Two unconfirmed responses on January 14th have later been confirmed.

Safety profile similar to the profile reported at ASH 2019, i.e. haematological toxicities were common but manageable – non-haematological toxicities were infrequent

Melflufen triple-class RRMM data highly competitive



	Melflufen Interim data from ASH except ORR	Xpovio Karyopharm US approval July 2019	Belantamab GSK In filing
Number of patients studied	93	122	97
Overall Response/Clinical Benefit Rate	26%*/37%	25%/39%	31%/34%
Duration of response	7.5 months	4.4 months	NR (≈7-8months)
Progression-free survival	4.0 months	3.7 months	2.9 months
Overall survival	11.3 months	8.0 months	NR (≈10months)
Share of patients with EMD	34%	22%	23%
Serious Adverse Event Rate	51%	58%	36% (excl. ocular tox.)
Non-hematologic toxicity (grade 3/4) reported in >5% of patients	Pneumonia 8.4%	Fatigue 25.2% Hyponatremia 20.3% Nausea 9.8% Pneumonia 8.9% Diarrhea 7.3% Sepsis 5.7% Hypokalemia 5.7% Mental status 5.7% General det. 5.7%	Keratopathy/ 27.4% Blurred vision Hypercalcaemia 7.4% Pneumonia/ 6.3% Lung infections

* ORR number is final ORR, all other melflufen data from Interim presentation at ASH, ORR was 24% at ASH

Positive HORIZON read: Submission and US commercialization of melflufen on track – key focus 2020

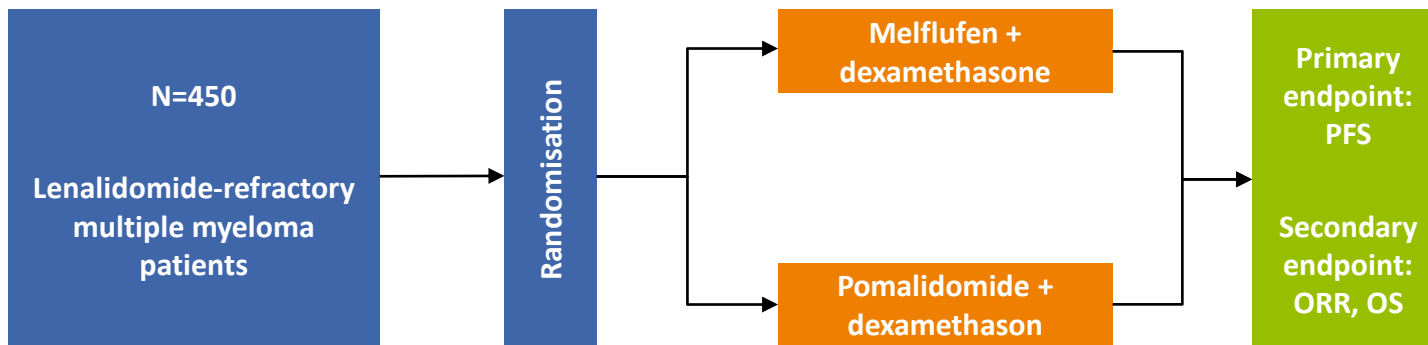


- Submission is on track for end of Q2 2020 with a potential launch around year end
- Early Access Program in the US to be launched as soon as feasible in RRMM patients
 - Patient population without treatment options but COVID-19 makes environment challenging
- US Commercialization build-up ongoing, 30 FTE by end March 31, key positions in place
 - The momentum in the build up process is ramping up during the coming quarters

Successful completion of enrollment in OCEAN – top line results expected H2 2020



Data to date provide high conviction for success in ongoing phase 3 study OCEAN



RRMM data from pomalidomide FDA label and O-12-M1 study

Treatment	ORR	CBR	Median PFS	Median DOR	Median OS
Melflufen + Dexamethasone	31%	49%	5.7 months	8.8 months	20.7 months
Pomalidomide + Dexamethasone	24%	NR	3.6 months	7.0 months	12.4 months

Pomalidomide shares resistance mechanism with lenalidomide

Average IMiD free period was significant in pomalidomide registration study

- Only 29% received lenalidomide as last treatment

Lenalidomide used more aggressively today

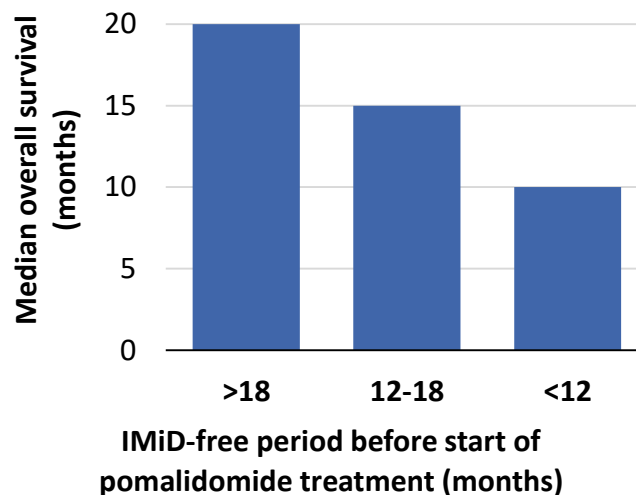
- Median maintenance duration 24 months instead of 10 months

In OCEAN all patients have failed on lenalidomide within 18 months

- Vast majority has lenalidomide as last treatment

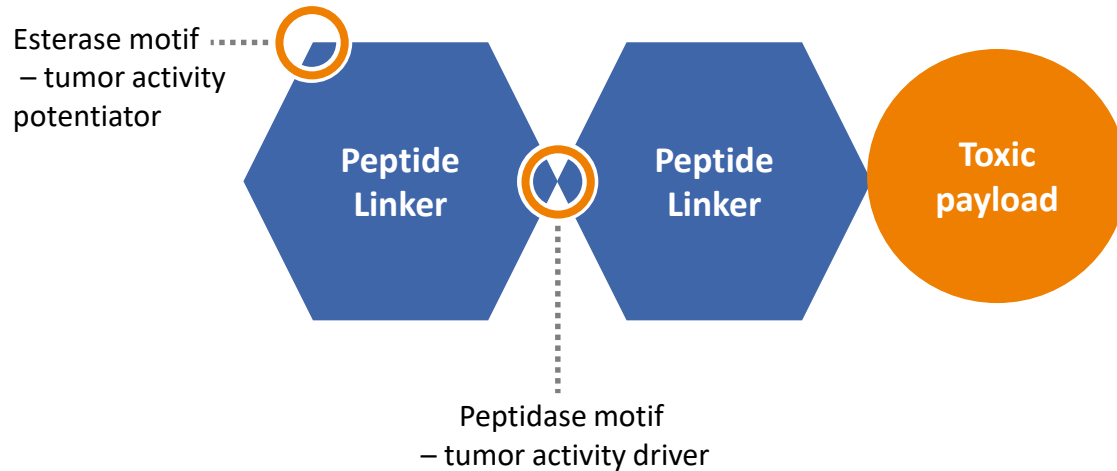
No assumptions have been made in OCEAN power calculation to account for increased cross resistance

Pomalidomide efficacy decreases for recent lenalidomide failures



Source: Pomalidomide with Low Dose Dexamethasone Is Effective Irrespective of Primary or Secondary Resistance to Lenalidomide but the IMiD-Free Interval Is Important (Dimopoulos et. al. ASH poster 2016).

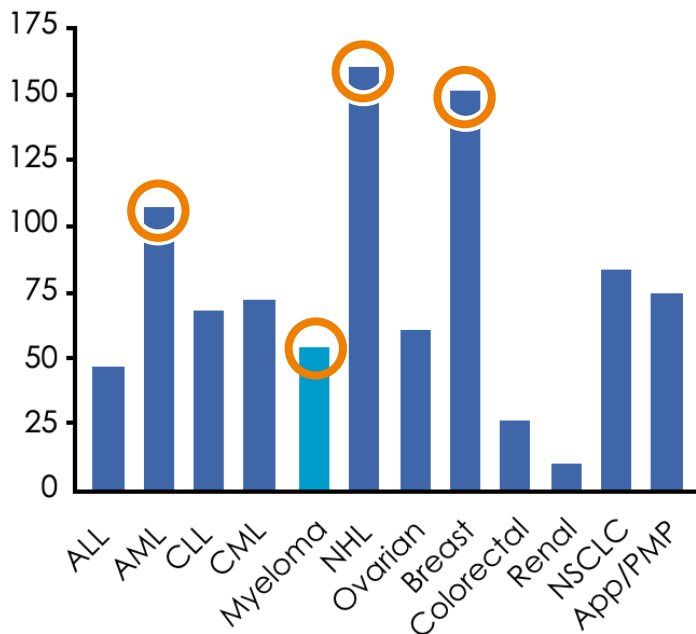
Unique Peptide-Drug Conjugate (PDC) platform



- Targeted delivery of toxins to tumor cells
- Utilizing unique enzymatic motifs
 - Peptidase motif necessary
 - Esterase motif potentiating

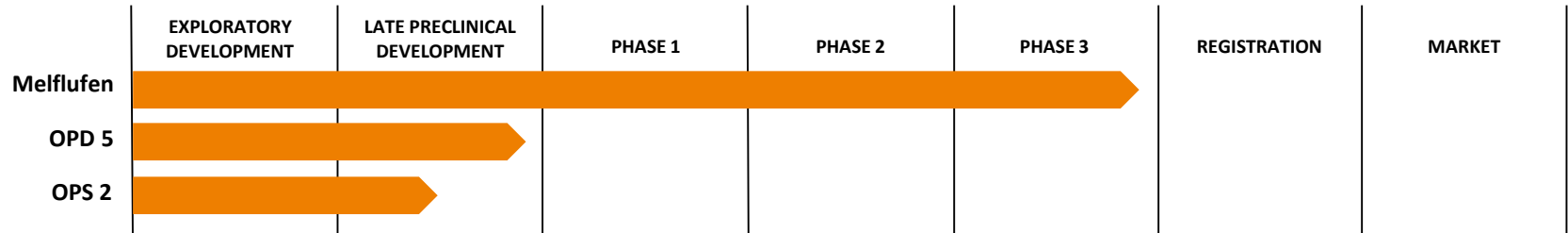
PDC platform exhibits significant therapeutic activity across several cancers

PDC Potentiation



- The PDC platform show good activity across a majority of cancers (data to the left on patient material)
- Based on the PDC platform, Oncopeptides have developed a portfolio of novel molecules
- Lead compound melflufen is focused on multiple myeloma and AL amyloidosis
- Indication expansion focus will be patients suffering from AML, NHL and breast cancer

Melflufen is currently in phase 3 - two more PDC candidates ready for the clinic in 2020 and 2021

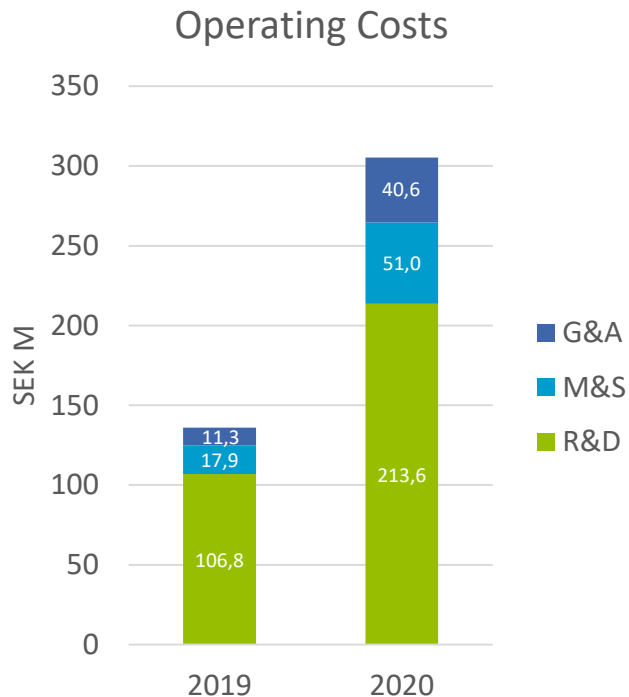


- OPD5 and OPS2 will be ready for the clinic in 2020 and 2021 respectively
 - OPD5 – specialized alkylating PDC candidate for high-dose treatment of patients (i.e. bone-marrow transplantation)
 - OPS2 – second generation PDC compound with an alkylating payload
- Both are novel molecules with composition of matter patents
- Full optionality to fully explore the PDC platform in 2021 and beyond

Directed share issue strengthened our balance sheet

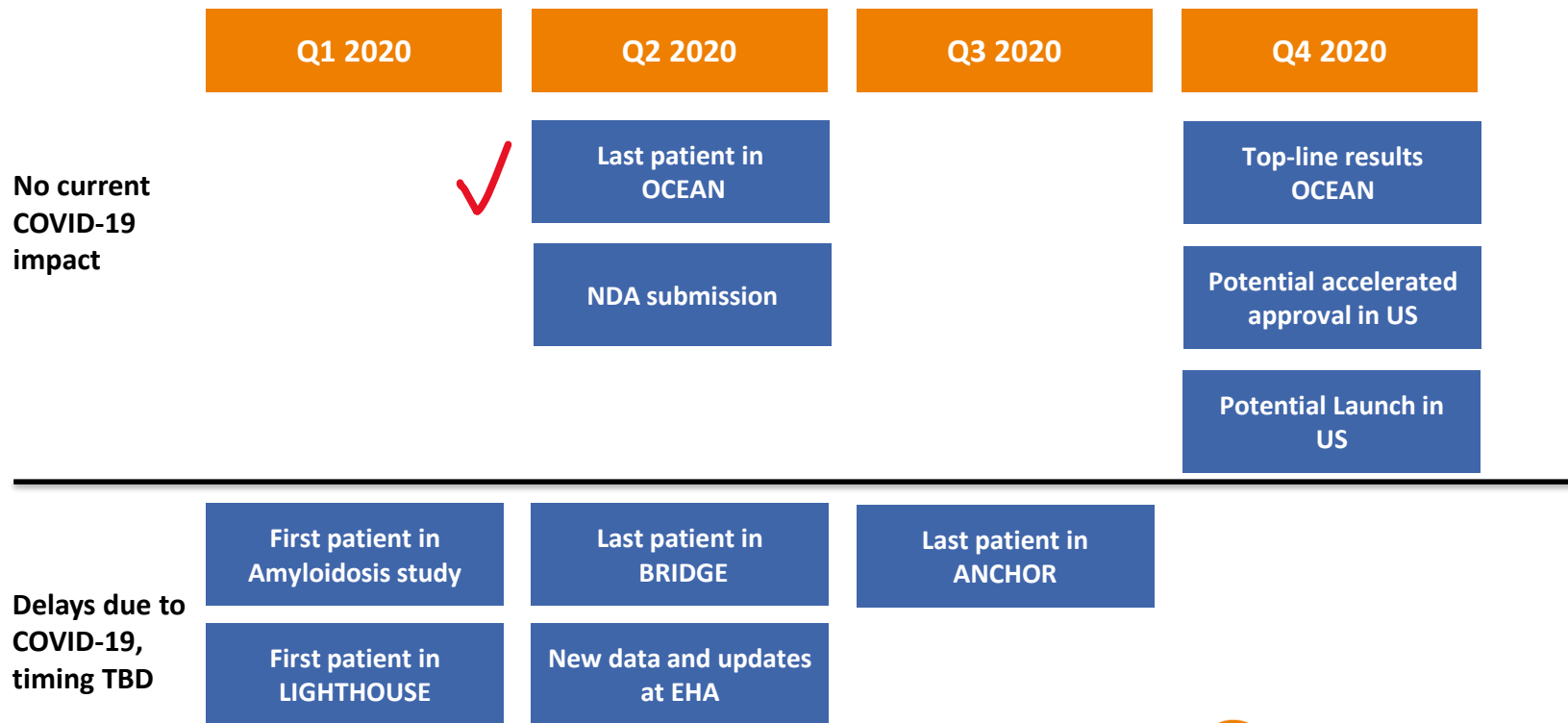
- High demand in directed share issue announced May 5
 - ~4x oversubscribed, upsized to maximum size
- Broad base of highly reputable international specialist investors participated
 - Deerfield
 - Farallon
 - Artisan
 - Octagon
- The transaction raised proceeds of SEK 1.4 billion before issue costs and is one of the largest ever conducted in the Swedish life science sector
- We see the support and interest from both existing shareholders and new international investors as a validation of our goals and strategic direction

Financial results for the period Jan – Mar 2020

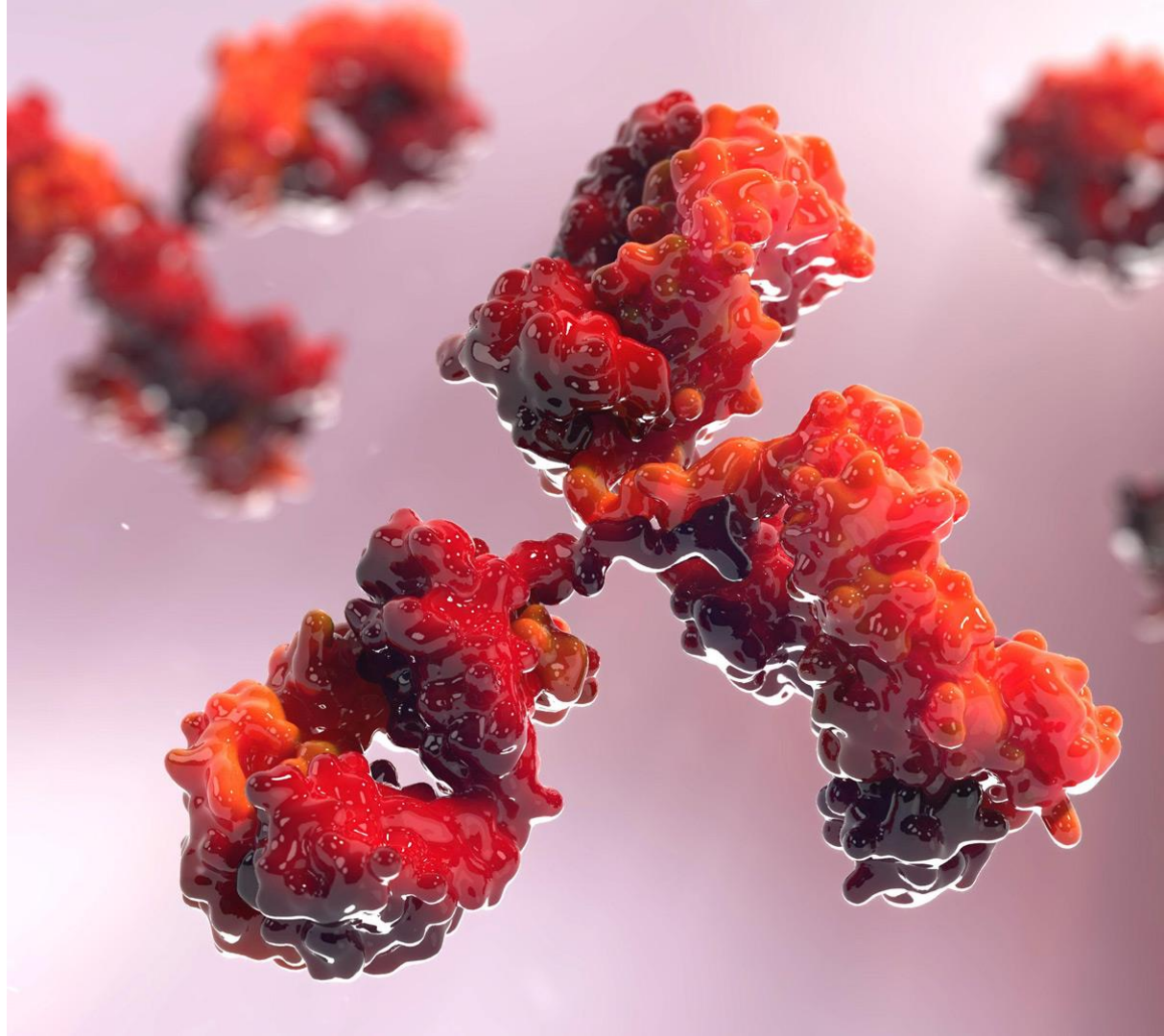


- Operating loss increased to SEK 296.9 M (loss:133.8)
 - R&D increase primarily due to increase in clinical & drug supply: SEK 158.3 M (73.1)
 - OCEAN SEK 77.7 M (37.6)
 - HORIZON SEK 25.8 M (11.0)
 - LIGHTHOUSE SEK 17.0 M (-)
 - ANCHOR SEK 7.4 M (13.2)
 - Build-up of commercial and medical relations explains increase in M&S
 - US subsidiary incl. admin SEK 44.3 M (8.5)
 - Limited effect of non-cash costs for incentive programs SEK 5.0 M (7.9)
- Cash flow from operating activities neg. SEK 312.8 M (neg. 142.8)
- Cash position was SEK 617.8 M (747.5) as of Mar 31, 2020
 - Directed share issue raising SEK 682.9 M in July 2019
 - Directed share issue raising SEK 1,413.9 M before issue costs after end of period in May 2020

News flow and timelines to be updated once COVID-19 situation becomes clearer



Q&A



***Thank you for
your attention!***

